Exhibit 24

Dott.ssa Patrizia Gargano
Consultant

Via Triboniano n. 14
04100 - LATINA

Dr.ssa Susanna Mecozzi
Managing Director
IC Pharma S.r.l.
P.zza G. Marconi 15
00144 - ROMA

INSPECTION READINESS ASSESSMENT AND GMP AUDIT REPORT - JAN 14TH -16TH, 2019

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD
Chuannan, Duqiao, Linhai
Zhejiang 317016, China

Preface

ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD produces many Active Pharmaceutical Ingredients which are supplied to European companies to be used for manufacturing of medicines which are marketed in the EU.
After detection on an impurity (NDMA), which is classified as a probable human carcinogen, into the Valsartan API, a joint EMA/EDQM for-cause inspection took place on September 2018 at ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD sites of Chuannan and XunQiao, in order to understand the root cause of the issue, in conjunction with the verification of compliance to GMP requirements for APIs as laid down in EU GMP Part II (ICH Q7) as well as to the other ICH pertinent guidelines (ICH Q8, 9, 10 and 11).
The inspectors team identified a total of 17 deviations (9 Major and 8 other).
A CAPA Plan was issued by ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD and submitted to the Authorities who recently replied that, after their evaluation, such a plan is considered not sufficient to rectify the deficiencies found on the Valsartan process and on the Quality Systems, then a follow-up inspection will be necessary to assess the implementation of the Corrective Actions.

Summary

The CAPA Plan implementation status in terms of the identified Corrective Actions to remove root causes of the issue and to avoid its recurrence, as well as any Preventive Actions taken to assure similar deviations could not occur in the future, was evaluated by the Auditors, especially concerning the Major deviations and in light of the Inspectors comments, which expressed in many cases that the Company's answers are not considered as sufficient for a satisfactory or complete removal of the detected deviations. Some gaps, misinterpretations, mistakes or weaknesses were identified by the Auditors during the visit and will be described in details in the following sections of the audit report.

As a general evaluation, it could be stated that Huahai Company performed a lot of good work that should be refined and completed as per the Auditors recommendations, so to be ready for the joint re-inspection, which will be performed in coming March.

Besides the technical observations and suggestions (which are specifically related to each of the deviations detected by the Inspectors and to their comments about the CAPA, as reported ahead), it is strongly recommended to follow the below indicated general rules and approach:

- During the re-inspection, most of the effort must be put by the Company on giving the evidence that the CAPA plan is robust and effective to prevent that a similar issue will re-occur in the future.

Dott.ssa Patrizia Gargano
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04100 - LATINA

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IC Pharma S.r.l.
P.zza G. Marconi 15
00144 - ROMA

- Said in other words, the Company must demonstrates with evidence that the lesson has been learned and that all the deficiencies which allowed the issue to happen, plus the additional detected deviations, were well understood, agreed and removed.
- Defending what happened and what was done in the past, even if it could be reasonably justified or explainable, is useless at this point of the story.
- It is strongly recommended that all the activities with a GMP relevance are performed by people belonging to the Quality organization or under the QA supervision, because they have the proper competences and responsibilities. Resources should be arranged accordingly.
- The number of people able to speak in English of technical topics should be increased, so to assure a proper understanding by Inspectors when the good work done by Huahai will be explained. Ideally such people should be the same subject matter experts and should belong to the Quality organization. If this is not the case for all the matters, each expert should be helped by a specifically identified person, having a technical background so able to translate into a proper English the topic under evaluation.

Visit Diary

During the visit, all the requested documentation was readily available, with few exceptions. Notwithstanding the enormous effort put in place by all the Huahai involved people, a complete understanding by the Auditors was not so easy, due to the language and cultural barriers; it was really difficult to get the architecture of the technical documentation, and the purpose or link between similar documents, such as versioning or addition of suffix to the document number.

The agenda shared in advance of the visit was quite strictly followed, with exception of the optional visits to the QC labs and the Valsartan Workshops, which were not performed because also the third day was fully utilized to review the documentation.

In the following section, a brief diary per each day of the visit is reported; the detected observations are written in italic characters (if any). At the end, a list of the same observations, with recommendations and suggestions is also reported.

1. **Day 1 (January 14th 2019):**

The opening meeting, chaired by Mr Chai, started around 9:00 as planned; all the people in the room presented themselves; the requested general information were given as slides presentations by Mr. Wayne Chen (Attachment 1 and 2).

Before starting with the planned activities, Huahai requested to the Auditors to perform a quick reading and evaluation of the report dealing with the NDMA results discrepancy between Huahai and the Official Medicines Control Laboratories of Ireland; such report was ready to be submitted to the Authorities on that same day. The investigation was found to be essentially good: the origin of the results discrepancy was successfully detected and a proper CAPA plan identified, while the narrative and the

Dott.ssa Patrizia Gargano
Consultant

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Managing Director
IC Pharma S.r.l.
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00144 - ROMA

wording used was found to be not always appropriate, so then some suggestions to improve the document were verbally given; the final version was not seen.

Then the two Auditors began the revision of Deviations narrative, related submitted CAPA + final Inspectors Comments by splitting themselves on **D1 (ex Def.n.15)** and **D2 (ex Def.n.3).**

The revised Standard Management Procedures SMP-023 Risk Management Procedure as well as SMP-018 Change Control System were read for review and found satisfactory.

The Risk Assessment Report RARC-20180904-2 about Nitrosamine Impurities for Huahai API,s (Xunqiao Site), updated as version 03 to include additional factors as requested by the Deficiency n.15, was evaluated and a "copy and paste" error was found on page 12/32, where it is reported that the Nitrite results were below LOD or not detectable on the 3 batches of water tested in October 2018, while 0.0057 ppm were found in one case. The document *must be corrected with the proper results and the related impact/contribution/risk from the potable water should be re-evaluated and consequently commented.*

The RAR about Candesartan API and the one related to Candesartan historical changes were evaluated too.

The Auditors found rather difficult getting a complete picture of the RAs performed by Huahai, needed to understand the evolution/expansion of the risk evaluation performed; consequently it was difficult to assess if all the various APIs, the related processes, all the other potential contributing factors and the historical changes already implemented had been properly evaluated for identifying the needed actions to mitigate and control the risks of impurities formation or presence, as requested by the initial Deficiencies and following Inspectors comments; then *it is recommended to prepare a Technical Report or a Summary where all the RARs completed as well as the ones still in progress are mentioned and briefly described, with reference to a list or to a scheme where it will be possible to easily identify the document numbers and related links, and also showing with evidence that all aspects have been evaluated (where and when), and all necessary actions and controls identified and implemented.* A document written in very simple and good English will be helpful to support the Huahai experts on answering to some really important questions and for removing still remaining doubts of the Inspectors about the most relevant consequence of the suffered issues, that is to say a possible recurrence of the problem: demonstrating with evidence to have gained a complete knowledge of the issue, and then also how to prevent the same issue could happen again in the future is essential to restore the Inspectors/Authorities confidence in the Huahai Quality Systems.

In relation to **D3 (ex Def. n.4), point a and c,** the new version of the SMP-011 "Customer Complaint & Customer Quality Event Management Procedure" was evaluated by both the Auditors and found not appropriate to remove the deficiency and to satisfy the final Inspectors comments.

2. **Day 2 (January 15th 2019):**

A revised text of SMP-011 was proposed by the Auditors and a draft was given to Huahai, with new definitions of Customer Complaints and different responsibilities assignment. The most important change to be implemented is that all the customers inquiries which have a technical as well as an even vague product quality related content, must be evaluated within and by the Quality Assurance organi-

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zation; this approach will exclude only the pure and clear commercial requests (then the ones related and limited to products price and any other similar topic or logistic arrangements in terms of timing, quantities etc.) so to prevent that any potential quality issue is underestimated or not caught by the Quality Systems. All activities which are described and regulated by procedures belonging to the Quality Systems, having even a minimal GMP impact must be executed by GMP competent and trained people; departments outside the Quality Systems and Quality Assurance supervision cannot perform activities with a GMP impact. For example the Sales Department could act as an interface with customers but without performing any scrutiny or filtering on technical or even not well clear, then potential products quality related requests. *A new version of the SMP-011 is needed, based upon the above described approach and discussed revised definitions (initial evaluation by QA of all customers inquiries to be categorized as justified/not-justified Customer Complaints, which could be further subdivided and categorized into confirmed/not-confirmed quality complaints based upon the investigation outcome, for a proper counting and trending; for the same purpose, it should be well clear that the new forms/fields/way of proceed make evident which are the complained batches to be investigated); responsibilities must be re-assigned accordingly; it is also suggested to expand and enrich the description of the different phases to be executed, especially for the complaint investigation, so to have a more detailed guide and structured way to proceed for the management of this important Quality process (technicalities that could be useful for the investigation execution should be mentioned and used, such as the 5Ws, the Fishbone approach etc.). The document title should also be changed into "Customer Complaint Management Procedure".*

D3 (ex Def. n. 4) points b, d and e were not examined in details by the Auditors; *it is suggested to prepare a text/summary with very simple explanations (or reference to available documents) which directly reply to the Inspectors final comments, avoiding to repeat the justifications already given.*

After evaluation of the Inspectors comments to **D4 (ex Def. n. 1),** it was found that the same RARs Summary mentioned above will be useful. It is also suggested *to prepare the CAPA Plan implementation status, which will show all the actions still on-going, to be updated the day before the coming re-inspection (similar to the slides content, as presented to the Auditors during the opening meeting). All the specifications of materials which were revised as an action to control/avoid impurities formation/presence and triggered by the investigations and/or by the performed RAs must be collected, together with a summary of all the results obtained till now by applying the new specs.*

On evaluating **D5 (ex Def. n. 2) point a,** Auditors verified that in reality, as noted by the Inspectors, the revised specifications of crude Valsartan to control the azide content below 4.7ppm (which is effective since January 01st, 2019) had been issued at that time but not submitted to the Authorities either as Appendix 1a-3 or in support of the corrective actions to remove the ex Deficiency 2, and also that the CAPA for ex Deficiency 2 was erroneously classified as "completed". *The revised specs for crude Valsartan must be ready to be shown with all the results for azide content on crude Valsartan obtained till now, if any. (please refer to D4 as well).*

In relation to **D5 (ex Def. n. 2) point dii ,** *the SMP-018 "Change Control System"* was verified to locate/identify in the text of the new version where it is strengthened or highlighted how/why it is now impossible to implement activities prior to the opening of a change. *Even if quite simple, the text is clear so Huahai should call for the Inspectors attention on the section where also activities related to non-GMP*

Dott.ssa Patrizia Gargano
Consultant

Via Triboniano n. 14
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Dr.ssa Susanna Mecozzi
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IC Pharma S.r.l.
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related matters (such as the EHS aspects of processes or equipment, line etc.) are now covered by the Change Control procedure. However it is also suggested to further review this procedure to more effectively organize the Change Control process flow, in terms of timing and authorizations for doing activities; it could be really better if the procedure establishes that the process is divided into different phases, which are one by one approved by QA for implementation, such as for example: 1-opening of a change, 2-starting of activities to be done in parallel by different departments or people, 3-verification that all the different streams of actions are successfully completed allowing 4-the change is approved as a whole for implementation, or 5-for progressing with further actions which would lead the implemented change could be 6-finally approved for its regular use... An historical collection of all the changes which were implemented in the same date of change opening/approval and related evaluation/correction could be useful, but it should be shown only on specific request from the Inspectors.

In relation to **D9 (ex Def. n. 7)**, *SMP-025 "Reprocess and Rework Management Procedure" version 04 was read and commented: it was found sufficient to satisfy the requested reworked/reprocessed batches traceability by the use all times of the letter R or W added to the original batch number plus the reprocessed/reworked batches log book, which was introduced with the version 04 to overcome the issue. Execute examples of such log book would be really useful if shown to the Inspectors.* It is the Auditors opinion that it is not necessary to trail the use of reprocessed/reworked batches with addition of an R/W to the batch number of the "child" products, so then the procedure text must be revised accordingly.

In the late afternoon, a meeting was chaired by the Huahai President Mr. Chen together with the auditing team (Auditors, Huahai mainly involved people and LCM representatives); the overall situation was shared with comments and suggestions from the Auditors and from Dr. Lencioni of LCM to the Huahai people.

3. **Day 3 (January 16th 2019):**

The "Recording and review Procedure for Laboratory" (QC-021-12), as submitted to the Authorities with the CAPA Plan to remove **D12 (ex Def. n. 8),** was evaluated and it was found that the highlighted sections 5.7 to 5.7.1.2 are not appropriate to address the observations, as commented by the Inspectors. The *English translated SOP should be re-issued, highlighting the sections where the observation is properly addressed; also the related Appendix, where the detailed instructions about how the raw data must be reviewed are given to operators, should be translated and shown so to assure with evidence that repeated analysis as well as repeated injections are always and effectively searched, identified and retrieved for the needed collection of the primary analytical data to be evaluated.*

On reading the Inspectors comments to **D13 (ex Def. n. 9),** it was deemed necessary to prepare a written position as follows, together with a second version of the "Investigation of the Unknown RT 10.6 min Impurity in GC-MS method for Valsartan NDMA test", containing a more extended text to explain the work already done, plus some additional trials for an improved clarity:

"The identity of methyl valerate was justified by a spiking study based upon understanding and knowledge of the Valsartan process chemistry plus the evaluation of its boiling point in comparison to n-butyl acetate, confirmed by a GC-MS study on a Reference Material. However, justification is better described on version 02 of the investigation MVD-18091(R).

Dott.ssa Patrizia Gargano
Consultant

Via Triboniano n. 14
04100 - LATINA

Dr.ssa Susanna Mecozzi
Managing Director
IC Pharma S.r.l.
P.zza G. Marconi 15
00144 - ROMA

Since methyl valerate could be considered a known unspecified impurity and quantified as such, according to the ICH Q3 Guidelines, the specifications of Valsartan do not need to be updated because known unspecified impurities test is already present there.

Based upon what is reported above, the requested information (such as the recovery rate and a new method + full validation data) are not available but more extended description of the analytical work is given on the already mentioned version 02 of the investigation MVD-18091(R), which also includes duplication of trials on lot D5191-18-225, which is the sample ID in Fig 2 referred on section 3, so to properly complete with evidence the study conclusions.

The general approach to management and investigations of future unknown peaks is embedded into the recently revised Risk Management procedures, which will be applied to any process development or change as well as to new drugs introduction, and into the corrected approach to complaint notifications management: these new approaches, as designed, will be applied and are suitable to the purpose for all APIs manufactured now and in the future at the site."

It was agreed that the criteria for considering only peaks having the area bigger than the NDMA peak area, found during testing of Valsartan, cannot be scientifically justified so it should be removed from the GC-MS method.

D15 (ex Def. n. 5) point b comments were evaluated and it was found that *the revised procedure SMP-021 OOS/OOT Investigation Management is now covering the deficiency because all OOS batches are easily and immediately tracked by the OOS listing in the forms that are filled monthly: all OOS results are listed there including the related batch number; OOS trending is always performed within the APQR.*

For **D15 (ex Def. n. 5) point c**, *it is suggested to re-evaluate the analytical method and its validation, to see if elution of the mentioned impurity could be obtained within the sample injection (prolonging the elution time or the gradient?), instead of allowing a carry-over on following sample injection.*

For **D15 (ex Def. n. 5) point d,** *it should be better explained* (and also verified that the topic is properly and clearly covered in the investigation report by the operators/supervisor interviews description) *that the wrong dating was caused by a human error and that it was unlikely the field was filled in advance due to practical/physical difficulties (location of people/document when equipment are used to perform operations). Re-training of operators was the CAPA in conjunction to the clocks replacement so to show also the current date together with the time, which would help operators to write the correct date, preventing their potential error.*

For **D15 (ex Def. n. 5) point e,** *the identified root cause should be better explained, detailing the role of the two involved operators and their location during the valves opening/closing (two operators supervising each other), which was occurring on two different rooms, and the consequent impossibility to perform the supervision all the time; such impossibility is now eliminated by the valves re-location into the same room.*
On reading *the revised Recall procedure (SMP-013-08),* submitted to the Authorities in relation to **D16 (ex Def. n. 6),** *it was found that some descriptions and translations could be improved so a further revision would be beneficial.*

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Dott.ssa Patrizia Gargano
Consultant

Via Triboniano n. 14
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Dr.ssa Susanna Mecozzi
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IC Pharma S.r.l.
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00144 - ROMA

For what concerns the Recall Protocol, Auditors clearly found and then explained why the Huahai answer was not accepted by the Inspectors; *a deep revision of the Protocol is needed, with a very much different wording so to demonstrate the Recall purpose and process have been well understood by Huahai; a new text was proposed by the Auditors also including a correct re-assignment of the Recall Grade, from Grade 2 to Grade 1, according to the requirements of the same above mentioned Huahai procedure itself, where it is clearly stated that Grade 1 must be assigned to a Recall in case the drug might induce serious harms to health, and being the possible/potential mutagenic and genotoxic effects not reversible.*

A closing meeting was held at the end of the day: all the Huahai involved people was present together with Mr Min Li, Huahai Analytical Operations VP, the Auditors and the LCM Representatives: the visit outcome was shared and all the above described observations/suggestions/recommendations from the Auditors were read and explained.

Observations/Recommendations/Suggestions list:

D1 (ex Def.n.15): *The Risk Assessment Report RARC-20180904-2 about Nitrosamine Impurities for Huahai API,s (Xunqiao Site), updated as version 03, must be corrected with the proper results and the related impact/contribution/risk from the potable water should be re-evaluated and consequently commented.*

D2 (ex Def.n.3): *It is recommended to prepare a Technical Report or a Summary where all the RARs completed as well as the ones still in progress are mentioned and briefly described, with reference to a list or to a scheme where it will be possible to easily identify the document numbers and related links, and also showing with evidence that all aspects have been evaluated (where and when), and all necessary actions and controls identified and implemented.*

D3 (ex Def. n.4), point a and c: *A new version of the SMP-011 is needed, based upon the above described approach and discussed revised definitions (initial evaluation by QA of all customers inquiries to be categorized as justified/not-justified Customer Complaints, which could be further subdivided and categorized into confirmed/not-confirmed quality complaints based upon the investigation outcome, for a proper counting and trending; for the same purpose, it should be well clear that the new forms/fields/way of proceed make evident which are the complained batches to be investigated); responsibilities must be re-assigned accordingly; it is also suggested to expand and enrich the description of the different phases to be executed, especially for the complaint investigation, so to have a more detailed guide and structured way to proceed for the management of this important Quality process (technicalities that could be useful for the investigation execution should be mentioned and used, such as the 5Ws, the Fishbone approach etc.). The document title should also be changed into "Customer Complaint Management Procedure".*

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D4 (ex Def. n. 1): *It is suggested to prepare the CAPA Plan implementation status, which will show all the actions still on-going, to be updated the day before the coming re-inspection. All the specifications of materials which were revised as an action to control/avoid impurities formation/presence and triggered by the investigations and/or by the performed RAs must be collected together with a summary of all the results obtained till now by applying the new specs.*

D5 (ex Def. n. 2) point a: *The revised specs for crude Valsartan must be ready to be shown with all the results for azide content on crude Valsartan obtained till now, if any.*

D5 (ex Def. n. 2) point dii: *Even if quite simple, the text of SMP-018 Change Control System is clear so Huahai should call for the Inspectors attention on the section where also activities related to non-GMP related matters (such as the EHS aspects of processes or equipment, line etc.) are now covered by the Change Control procedure.*

D9 (ex Def. n. 7): *SMP-025 Reprocess and Rework Management Procedure version 04 was found sufficient to satisfy the requested reworked/reprocessed batches traceability by the use all times of the letter R or W added to the original batch number plus the reprocessed/reworked batches log book, which was introduced with the version 04 to overcome the issue. Execute examples of such log book would be really useful if shown to the Inspectors.*

D12 (ex Def. n. 8): *The English translated SOP "Recording and review Procedure for Laboratory (QC-021-12) should be re-issued, highlighting the sections where the observation is properly addressed; also the related Appendix, where the detailed instruction about how the raw data must be reviewed are given to operators, should be translated and shown so to assure with evidence that repeated analysis as well as repeated injections are always and effectively searched, identified and retrieved for the needed collection of the primary analytical data to be evaluated.*

D13 (ex Def. n. 9): *"The identity of methyl valerate was justified by a spiking study based upon understanding and knowledge of the Valsartan process chemistry plus the evaluation of its boiling point in comparison to n-butyl acetate, confirmed by a GC-MS study on a Reference Material. However, justification is better described on version 02 of the investigation MVD-18091(R).*

Since methyl valerate could be considered a known unspecified impurity and quantified as such, according to the ICH Q3 Guidelines, the specifications of Valsartan do not need to be updated because known unspecified impurities test is already present there.

Based upon what is reported above, the requested information (such as the recovery rate and a new method + full validation data) are not available but more extended description of the analytical work is given on the already mentioned version 02 of the investigation MVD-18091(R), which also includes duplication of trials on lot D5191-18-225, which is the sample ID in Fig 2 referred on section 3, so to properly complete with evidence the study conclusions.

The general approach to management and investigations of future unknown peaks is embedded into the recently revised Risk Management procedures, which will be applied to any process development or change as well as to new drugs introduction, and into the corrected approach to complaint notifications

Dott.ssa Patrizia Gargano
Consultant

Via Triboniano n. 14
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Dr.ssa Susanna Mecozzi
Managing Director
IC Pharma S.r.l.
P.zza G. Marconi 15
00144 - ROMA

management: these new approaches, as designed, will be applied and are suitable to the purpose for all APIs manufactured now and in the future at the site."

The criteria for considering only peaks having the area bigger than the NDMA peak area, found during testing of Valsartan, cannot be scientifically justified so it should be removed from the GC-MS method.

D15 (ex Def. n. 5) point b: *The revised procedure SMP-021 OOS/OOT Investigation Management is now covering the deficiency because all OOS batches are easily and immediately tracked by the OOS listing in the forms that are filled monthly: all OOS results are listed there including the related batch number; OOS trending is always performed within the APQR. Examples of the form filled as per the new procedure should be ready for showing to the Inspectors.*

D15 (ex Def. n. 5) point c: *It is suggested to re-evaluate the analytical method and its validation, to see if elution of the mentioned impurity could be obtained within the sample injection (prolonging the elution time or the gradient?), instead of allowing a carry-over on following sample injection.*

D15 (ex Def. n. 5) point d: *It should be better explained that the wrong dating was caused by a human error and that it was unlikely the field was filled in advance due to practical/physical difficulties (location of people/document when equipment are used to perform operations). It should be highlighted that re-training of operators was the CAPA, in conjunction to the clocks replacement so to show also the current date together with the time, which would help operators to write the correct date, preventing their potential error.*

D15 (ex Def. n. 5) point e: *The identified root cause should be better explained, detailing the role of the two involved operators and their location during the valves opening/closing (two operators supervising each other), which was occurring on two different rooms, and the consequent impossibility to perform the supervision all the time; such impossibility is now eliminated by the valves re-location into the same room.*

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D16 (ex Def. n. 6): *On the revised Recall procedure (SMP-013-08), some descriptions and translations could be improved so a further revision would be beneficial.*

A deep revision of the Recall Protocol is needed, with a very much different wording so to demonstrate the Recall purpose and process have been well understood by Huahai; a new text was proposed by the Auditors also including a correct re-assignment of the Recall Grade, from Grade 2 to Grade 1, according to the requirements of the same above mentioned Huahai procedure itself, where it is clearly stated that Grade 1 must be assigned to a Recall in case the drug might induce serious harms to health, and being the possible/potential mutagenic and genotoxic effects not reversible.